

## § 184.1443

this section do not exist or have been waived.

[50 FR 13560, Apr. 5, 1985]

### § 184.1443 Magnesium sulfate.

(a) Magnesium sulfate ( $\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$ , CAS Reg. No. 10034-99-8) occurs naturally as the mineral epsomite. It is prepared by neutralization of magnesium oxide, hydroxide, or carbonate with sulfuric acid and evaporating the solution to crystallization.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 183, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavor enhancer as defined in § 170.3(o)(11) of this chapter; a nutrient supplement as defined in § 170.3(o)(20) of this chapter; and a processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 13560, Apr. 5, 1985]

### § 184.1443a Malt.

(a) Malt is an enzyme preparation obtained from barley which has been softened by a series of steeping operations and germinated under controlled conditions. It is a brown, sweet, and viscous liquid or a white to tan powder. Its

## 21 CFR Ch. I (4-1-21 Edition)

characterizing enzyme activities are  $\alpha$ -amylase (EC 3.2.1.1.) and  $\beta$ -amylase (EC 3.2.1.2).

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), p. 110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418, or may be examined at the Office of Premarket Approval (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in § 170.3(o)(9) of this chapter to hydrolyze starch or starch-derived polysaccharides.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

[60 FR 32911, June 26, 1995]

### § 184.1444 Maltodextrin.

(a) Maltodextrin ( $(\text{C}_6\text{H}_{10}\text{O}_5)_n$ , CAS Reg. No. 9050-36-6) is a nonsweet nutritive saccharide polymer that consists of D-glucose units linked primarily by  $\alpha$ -1-4 bonds and that has a dextrose equivalent (D.E.) of less than 20. It is prepared as a white powder or concentrated solution by partial hydrolysis of corn starch, potato starch, or rice starch with safe and suitable acids and enzymes.

(b)(1) Maltodextrin derived from corn starch must be of a purity suitable for its intended use.

(2) Maltodextrin derived from potato starch meets the specifications of the Food Chemicals Codex, 3d ed., 3d supp. (1992), p. 125, which are incorporated by

reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418, or at the Division of Petition Control (HFS-217), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(3) Maltodextrin derived from rice starch meets the specifications of the Food Chemicals Codex, 4th ed. (1996), pp. 239 and 240, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51911, Nov. 15, 1983, as amended at 60 FR 48893, Sept. 21, 1995; 63 FR 14611, Mar. 26, 1998; 81 FR 5596, Feb. 3, 2016]

#### § 184.1445 Malt syrup (malt extract).

(a) Malt is the product of barley (*Hordeum vulgare* L.) germinated under controlled conditions. Malt syrup and malt extract are interchangeable terms for a viscous concentrate of water extract of germinated barley grain, with or without added safe preservative. Malt syrup is usually a brown, sweet, and viscous liquid containing varying

amounts of amylolytic enzymes and plant constituents. Barley is first softened after cleaning by steeping operations and then allowed to germinate under controlled conditions. The germinated grain then undergoes processing, such as drying, grinding, extracting, filtering, and evaporating, to produce malt syrup (malt extract) with 75 to 80 percent solids or dried malt syrup with higher solids content.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51613, Nov. 10, 1983, as amended at 73 FR 8607, Feb. 14, 2008]

#### § 184.1446 Manganese chloride.

(a) Manganese chloride ( $MnCl_2$ , CAS Reg. No. 7773-01-5) is a pink, translucent, crystalline product. It is also known as manganese dichloride. It is prepared by dissolving manganous oxide, pyrolusite ore ( $MnO_2$ ), or reduced manganese ore in hydrochloric acid. The resulting solution is neutralized to precipitate heavy metals, filtered, concentrated, and crystallized.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 186, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/](http://www.archives.gov/federal_register/)